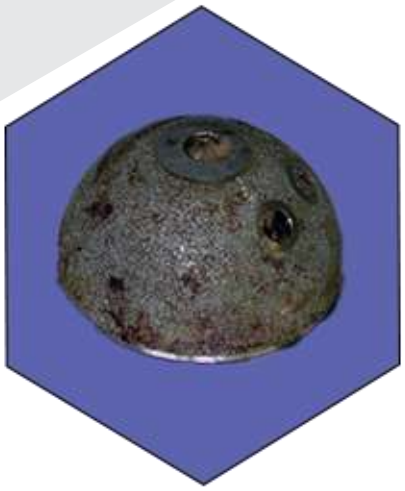
Cambridge Polymer Group



The Sulzer Recall: Process Failures and How to Find Them

Manufacturing Process Mitigation

Summary

In the early 2000's a major recall occurred in the orthopedic industry where growing evidence suggested thousands of metallic acetabular shells would require revision. Cambridge Polymer Group investigated and determined that they were associated with a change in the manufacturing process. CPG subsequently helped the manufacturer develop and validate the replacement process for this product and its successful relaunch.

Background

In 2000 Sulzer Orthopedics began to receive reports of increased rates of revisions of implants related to incomplete osseointegration following surgeries. Unlike more traditional cemented implants, porous implants are intended to encourage bone growth into carefully engineered porous surfaces. A lack of boney in-growth resulted in implants that never healed properly, causing patient discomfort and revision surgeries. Sulzer recognized that there appeared to be trends emerging related to lot numbers but could not isolate the root-cause and asked for CPG's help.

Analysis

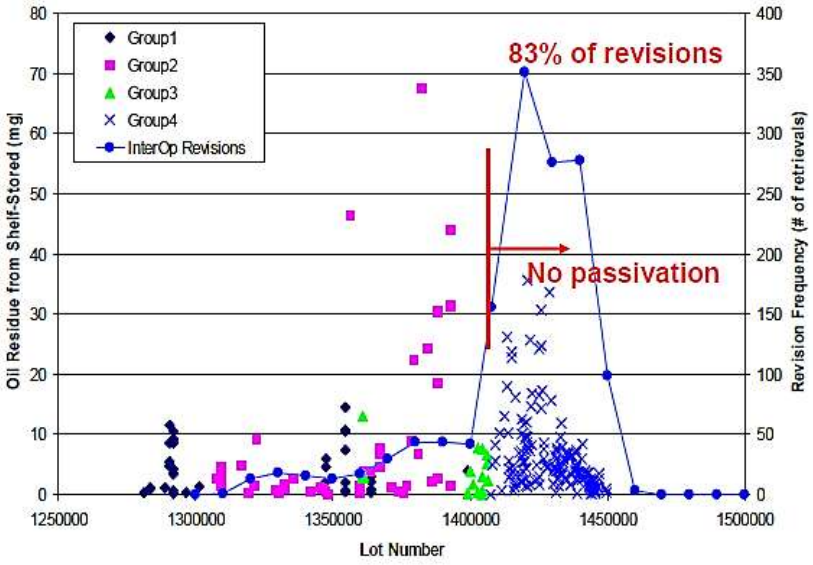
We developed an extraction and analysis method to isolate manufacturing residues left on the explants. The investigation demonstrated that Sulzer's manufacturing process was leaving behind a hydrocarbon-based lubricant. However, it was clear from the production data that the presence of the oil alone was not sufficient to explain the failures.

Discussion

After a process review, it became clear that the bulk of the acetabular shells that failed clinically had oil present but were also not subjected to a nitric acid passivation wash in a process change from prior lots. It is believed that the passivation step either removed endotoxins (or some other toxic component) that were carried within the lubricant. CPG started a new task group at ASTM on medical device cleaning.

Key Points

- "Trivial" manufacturing changes must still be validated
- Root-cause analysis requires more than one discipline
- CPG actively involved in ASTM standard development



Cambridge Polymer Group, Inc. is a contract research laboratory specializing in materials. We partner with our clients to solve the world's toughest polymer problems utilizing our multi-disciplinary research team and full service laboratory.

We work with clients throughout the product life cycle to:

- Develop new materials
- Design prototypes for proof-of-concept studies
- Create and execute experimental design
- Validate and verify manufacturing processes
- Perform root-cause analysis in product failures

Cambridge Polymer Group, Inc. was founded in 1996 to provide a cost-effective resource for testing, research and development to clients who need periodic access to Ph.D.-level scientists and their support structure. We have developed a host of testing methods and materials for our clients, which number more than 1,000.

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